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August 2, 2013

Ms. Sharon Kapsch
Office of Surveillance and Biometrics
Division of Post market Surveillance
Food and Drug Administration
Bldg. WO66
Silver Spring, MD 20993-0002

Subject: Request for a Retrospective Alternate Summary Report for retrospective post-market study of INFUSE® Bone Graft

Dear Ms. Kapsch,

Following a phone conversation with William Huff on July 24, 2013, and at Mr. Huff's suggestion, Medtronic Spinal & Biologics ("Medtronic") submits this letter requesting Summary Reporting for approximately (b)(4) retrospective MDRs. The MDRs pertain to a retrospective post-market study that was conducted for the INFUSE® Bone Graft ("INFUSE") product (the "Retrospective Study"). The study was conducted in the 2006–2008 timeframe, and included data from the 2002–2006 timeframe. This letter provides background information regarding the Retrospective Study, as well as certain details requested by Mr. Huff (e.g., a summary break down of event types and approximate number in each category), per our phone conversation on July 24.

Retrospective post-market study based MDRs:

(b)(4)

[redacted]

Product codes (as requested in the phone call)
The product code for INFUSE® Bone Graft is 'NEK'. Since some of the events also included the use of other Medtronic devices (screws, rods, intradiscal spacers, plates, etc.), the Medtronic devices will be coded accordingly depending on the pro-code that we currently use for submission of our device-related events (including 'KWP' and other codes).

Tabular breakdown and explanation of Death, Serious Injuries and/or Malfunctions (as requested):
As Mr. Huff requested, the table below shows the breakdown of INFUSE events by category of death, serious injury, and malfunction events in the Retrospective Study data set. Please note that while reviewing and assessing the details of the data set, we have identified INFUSE events that are not reportable as per our MDR decision tree, hence the MDR count from the (b)(4) identified events may be less than (b)(4). However, there are also some malfunction events that involve other Medtronic devices (used in during the study with INFUSE) that may be reportable, and we are requesting summary reporting of those events along with the INFUSE events. We do not expect these other device-related events to exceed (b) MDRs.

Category	Approx. # of INFUSE events	Comments and Explanation
Death	(b)(4)	(b)(4)
Serious Injury		
Malfunction – INFUSE Related		
Malfunction – Other Medtronic devices.		

Please let me know if you need any further data to support this Retrospective ASR request, or if you have questions. I can be reached at the email address and phone number below. Thank you for your assistance in this matter.

Regards,

Huzefa Mamoola
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U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FDA eMDR generated Form 3500A

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	1030489-2014-00628
UF/Importer Report #:	
Form Code:	

A. PATIENT INFORMATION

(b)(6)

[redacted]

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

(b)(6)

(b)(6)